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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,693	03/22/2004	Venkataramana Vijay	VIJ-004	8738

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EXAMINER

FOSTER, MARLEE CHRISTINE

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 11/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

NT

Office Action Summary

Application No.

10/805,693

Applicant(s)

VIJAY, VENKATARAMANA

Examiner

Marlee C. Foster

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>12 July 2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 4, 6, 7, 8, 10, 12, 18, 19, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Vorwerk (U.S. Patent 2,038,916). Vorwerk discloses, in the figures and claims, a scissors instrument, comprising a first blade (4), a second blade (5) defining a cutting interface with said first blade, a tissue piercing tip (7) of substantially smaller diameter than said first and second blades projecting from one of said first and second blades, and a handle operable to move said first and said blades relative to each other. As Vorwerk discloses in figure 1, the tip extends beyond the first blade and is aligned with the upper cutting surface. When the instrument of Vorwerk is

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in the closed position, the tip is parallel to the lower surface. The lower surface of the second blade (4) is substantially straight. The handles of Vorwerk, shown in figures 1, 3-5 include rings so the user may grasp the rings and actuate the blades.

Regarding claims 18 and 19, the first and second blades are slightly tapered at the ends, which define the tissue-piercing tip. The second blade (4) includes a step to define the tissue-piercing tip. Regarding claim 21, the tip extends beyond the first and second blades of the device.

4. Claims 20 is rejected under 35 U.S.C. 102(b) as being anticipated by Koch (U.S. Patent 3,979,826). Koch discloses a scissors instrument, comprising scissors blades, a handle (4) operable to move at least one scissors blade relative to the other (3), and a tissue-piercing tip (7) having a substantially constant diameter in relation to said scissors blades.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vorwerk (U.S. Patent 2,038,916) in view of Ryan (US 2004/0186484). Vorwerk discloses the invention substantially as claimed, with a first and second blade, a tissue-piercing tip, and handles that actuate the blades. However, Vorwerk is silent with regards to the diameter of the tip. Ryan teaches an instrument that has a 25-gauge diameter (paragraph 0013) so that it may allow for a small incision. Reducing the size of the incision will not only speed recovery time for the procedure, but reduce pain and the change of infection. Therefore it would have been obvious to one of ordinary skill in the art to provide the instrument of Vorwerk with a tissue-piercing tip of 25-gauge diameter to allow for cutting and tissue manipulation within a small incision.

8. Claims 3, 5, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vorwerk (U.S. Patent 2,038,916) in view of Yusuf et al (U.S. Patent 6,915,578). Vorwerk discloses the invention substantially as claimed, with a first and second blade and a tissue-piercing tip. Regarding claim 3, Examiner notes that the device of Vorwerk may be oriented with either blade as an "upper" or "lower" blade. The orientation of the Vorwerk's device does not affect the function of the tip. The tip is shown to be coupled to an upper blade, but may be used so that the tip is coupled to the lower blade.

Regarding claims 5 and 23, Yusuf et al. teach a similar device, with a tissue-piercing tip that extends at an equal length to the cutting blades and handles for actuating the cutting blades. The tip of Yusuf et al is located at the ends of the blades, and may pierce tissue, but does not extend substantially beyond the blades.

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Yusufov et al additionally teach the device usable in either orientation (col. 1, line 35), to adapt for either right-handed or left-handed users. Therefore it would have been obvious to one of ordinary skill in the art to orient the device of Vorwerk with the tissue-piercing tip either pointed up or down, to configure it for right- or left- handed users.

9. Claims 9 and 11 rejected under 35 U.S.C. 103(a) as being unpatentable over Vorwerk (U.S. Patent 2,038,916) in view of Hildebrandt et al. (U.S. Patent 3,651,811). Vorwerk teaches the device substantially as claimed. Hildebrandt et al. disclose a similar scissors instrument, with a Castroviejos handle and blades (4 and 5) that a curvature or taper to a lower surface, as shown in figures 1 and 2. The handles are provided to make actuation of the blades easier for the surgeon, and reduce the risk of injury. The blades are provided at a curvature to reduce tissue accumulation while cutting (col. 3, lines 6-12). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to provide the device of Vorwerk in view of the teaching of Hildebrandt et al., to increase ergonomic comfort for the surgeon and improve the precision of the cutting.

10. Claims 13-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vorwerk (U.S. Patent 2,038,916) in view of Follmer et al (US 2003/0018346). Vorwerk et al. teach the device substantially as claimed, but fail to teach a tubular, flexible, catheter shaft supporting the cutting blades of the device. Follmer et al. teach a cutting device mounted at one end of a tubular, flexible catheter (12). This device allows for easier manipulation of tissue within the body lumen by allowing the surgeon to access the tissue (paragraph 0030). Therefore, it would have been obvious to one of ordinary

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skill in the art at the time of the invention to provide the device of Vorwerk in view of the teaching of Follmer et al., and allow the cutting device to navigate through tortuous body lumen to remove tissue.

11. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Vorwerk (U.S. Patent 2,038,916) in view of Giordano et al. (U.S. Patent 5,980,556). Vorwerk et al. teach the device substantially as claimed, but fail to specify the cross-sectional geometry of the scissors device. Giordano et al. teach a triangular cross section for the cutting blades and cutting tip, in figure 2, reference 4. Giordano et al. teach that the specific forces that interact with the actuating blades allow for a deflection of the cutting surface, thus making the displacement of the blades easier. Therefore, it would have been obvious to one of ordinary skill in the art to provide the blades of Vorwerk in a triangular cross sectional area in order to ease the deflection of the cutting blades.

12. Claims 24- 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vorwerk (U.S. Patent 2,038,916) in view of Hildebrandt et al. (U.S. Patent 3,651,811). Vorwerk discloses the invention substantially as claimed, however teaches an alternate method of use for the device. Hildebrandt et al. teach a method of using the scissors device to insert the instrument and incise and cauterize the blood vessel (col. 3, lines 65-75). This method disclosed in claims 25 and 26 is the obvious method of using a scissors device to cut a blood vessel. Therefore, it would have been obvious to one of ordinary skill in the art to use the device of Vorwerk in the method disclosed in the teaching of Hildebrandt et al. to cut or and pierce the tissue.

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Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Slater et al. (U.S. 5,392,789) disclose a similar device.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marlee C. Foster whose telephone number is (571) 272-5072. The examiner can normally be reached on Monday to Friday 8:00am to 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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ANH TUAN T. NGUYEN
SUPERVISORY PATENT EXAMINER
